

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH CERTIFICATE OF NEED (CON) COMMISSION MEETING

Wednesday, June 13, 2007

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call To Order

Vice-Chairperson Goldman called the meeting to order at 9:13 a.m.

A. Members Present:

Norma Hagenow, Chairperson
Edward B. Goldman, Vice-Chairperson
Peter Ajluni, DO
Bradley N. Cory
Dorothy E. Deremo
Marc Keshishian, MD
Michael A. Sandler, MD
Kathie VanderPloeg-Hoekstra
Michael W. Young, DO

B. Members Absent:

Adam Miller

C. Department of Attorney General Staff:

Ronald J. Styka

D. Michigan Department of Community Health Staff Present:

Lakshmi Amarnath
Umbrin Ateequi
Jan Christensen
William Hart
John Hubinger
Joette Laseur
Irma Lopez
Andrea Moore
Stan Nash
Taleitha Pytlowanyj
Brenda Rogers

II. Review of Agenda

Motion by Vice-Chairperson Goldman, seconded by Commissioner Ajluni, to approve the agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interest

No conflicts were stated at this time.

IV. Review of Minutes – March 13, 2007

Commissioner Sandler stated that under the Legislative Report, item XIII, it should also state that the Department will set-up a meeting with House Representative Kathy Angerer to discuss Senator George's issues.

Motion by Commissioner Deremo, seconded by Commissioner Young, to accept the March 13 Minutes with modifications. Motion Carried.

V. Public Comment for Action Items (i.e., VI)

Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units

Barbara Jackson, Economic Alliance for Michigan
Anne Mitchell, UMS/GLL

Psychiatric Beds

Phyllis Adams, Dykema Gossett

VI. Air Ambulance (AA) Services

A. Review of Proposed Language

Ms. Moore stated that the AA Workgroup had completed their task and she provided a summary of the Workgroup's recommendations including an overview of the draft/technical changes to the Standards. Discussion followed.

B. Commission Proposed Action

Motion by Commissioner Sandler, seconded by Commissioner Young, to approve the language and move it forward for a Public Hearing. Motion Carried.

VII. Neonatal Intensive Care Unit (NICU) Services/Beds

A. Review of Proposed Language

Ms. Moore provided a brief overview of the NICU Services/Beds Standards. Discussion followed.

B. Commission Proposed Action

Motion by Commissioner Deremo, seconded by Commissioner Ajluni, to approve the language and move it forward for a Public Hearing. Motion Carried.

VIII. Psychiatric Beds and Services – MDCH Report

A. Commission Discussion

Ms. Moore spoke on behalf of the Department. She stated that the Workgroup plans to meet again on July 27. Commissioner Deremo provided the Commission with a brief update as well. Discussion followed.

B. Commission Action

The Commission decided to take no action at this time.

IX. UESWL Services/Units – MDCH Report

A. Commission Discussion

Ms. Rogers provided the Commission with the Department recommendations. Ms. Rogers stated that the Department believes Lithotripsy should continue to be regulated. Discussion followed.

B. Commission Action

Motion by Commissioner Goldman, seconded by Commissioner Sandler, to accept the Department's recommendations with the understanding that the Department will provide more data and will make technical changes to the language to be presented to the Commission at the September meeting. Motion Carried.

X. Magnetic Resonance Imaging (MRI) Services Statement

A. Commission Discussion

Mr. Christensen provided a brief update. He stated that the Department recommends MRI Services should continue to be regulated at this time. Discussion followed.

B. Commission Action

Motion by Commissioner Goldman, seconded by Commissioner Ajluni, to accept the Department's report and look at quality and cost to make a more substantial decision in 2009. Motion Carried.

XI. Cardiac Catheterization (CC) Services Standard Advisory Committee (SAC) – Status Report

Ms. Joseph, Chairperson of the CCSAC, provided a brief update on the progress of the SAC. She stated the SAC has concluded its process and a full report will be provided in September. Discussion followed.

XII. Open Heart Surgery (OHS) Services SAC – Status Report

Ms. Ateequi spoke on behalf of the OHSSAC due to Mr. Delaney, the Chairperson of the SAC, not being able to attend. Ms. Ateequi read the written report (Attachment A) that Mr. Delaney provided in regards to the progress of the SAC. Discussion followed.

Break from 10:33 a.m. to 10:50 a.m.

XIII. Hospital Bed Fact-Finding – MDCH Report

Mr. Christensen provided a brief update and summarized the written report (Attachment B) regarding the progress of the Hospital Bed Fact-Finding Workgroup. Discussion followed.

XIV. Computed Tomography (CT) Scanner Services and Nursing Home & Hospital Long-Term Care (NH-HLTC) Unit Beds – SAC Appointments

Chairperson Hagenow provided a brief update on the appointment progress. She informed the Commission that the appointments have been made and letters will be sent out within the next few days. She stated that the member report will be posted on the CON website by the end of the week. Commissioner Sandler suggested that the Department poll the CTSAC members to ensure that a quorum would be present at the first meeting because he did not feel enough members would be able to attend on that date. Discussion followed.

XV. Standing New Medical Technology Advisory Committee (NEWTAC) – Report

Commissioner Keshishian provided a brief update regarding NEWTAC. He informed the Commission that the NEWTAC will be discussing the 3 services that Senator George recommended be added under CON regulations. Discussion followed.

XVI. Legislative Report

Mr. Christensen provided a brief update in regards to the Senator George letter. He stated that Senator George is not going to pass any legislation at this time and that the Department is planning to have another meeting with him. Discussion followed.

XVII. Compliance Report

Mr. Christensen provided a brief update. Discussion followed.

XVIII. Administrative Update

Mr. Hart provided a brief update. Discussion followed.

XIX. CON Program Update

CON Program provided the Commission with a written report (Attachment C). Ms. Rogers provided a brief summary of the report. Discussion followed.

XX. Future Meeting Dates

September 18, 2007

December 11, 2007

XXI. Public Comment

Matt Jordan, Xoran Technologies
Bob Meeker, Spectrum Health
Lody Zwarensteijn, Alliance for Health
Patrick O'Donovan, William Beaumont Hospitals
Larry Horwitz, Economic Alliance for Michigan

XXII. Work Plan

Ms. Rogers provided a brief overview of the Draft Work Plan. Discussion followed.

Motion by Commissioner Goldman, seconded by Commissioner Keshishian, to accept the Work Plan. Motion Carried.

XXIII. Adjournment

Motion by Commissioner Deremo, seconded by Commissioner Keshishian, to adjourn the meeting at 12:18 p.m. Motion Carried.

Date: June 13, 2007

From: James K. Delaney, Chairperson, Open Heart Surgery SAC

To: Norma Hagenow, Chairperson, Certificate of Need Commission
Edward Goldman, Vice- Chair, Certificate of Need Commission

RE: **Open Heart Surgery Standard Advisory Committee (OHS SAC) Update**

The OHS SAC began meeting in January 2007 with the Charge to address the following issues, as approved by the CON Commission on June 21, 2006:

1. Review and consider public reporting of risk adjusted outcomes.
2. Review and determine minimum institutional and physician volume requirements in the Certificate of Need Review Standards for Open Heart Surgery Services.
3. Review and consider mandating the participation in a quality/risk adjusted outcome/database.
4. Report to the Commission at the December 12, 2006 meeting about any additional priority issues not in the Charge.
5. How to demonstrate need and compliance looking at geographic locations, volume, length of commitment, and types of procedures.

I applaud the Commission for selecting such a talented and conscientious panel for the OHS SAC. The group takes our Charge and mission for the people of the State of Michigan very seriously. The Committee has completed all of the elements of the charge, with finalization of draft language to the CON Review Standards for Open Heart Surgery to be completed at the July 11th SAC meeting. We expect that a full report of recommendations will be available for your September meeting. A summary of some key recommendations made by the SAC in response to the above charges follows:

- The SAC is in agreement that we do not have the means or knowledge at this time for public reporting to occur accurately and responsibly, and therefore, does not recommend public reporting of risk-adjusted outcomes at this time. Given the fact that the Michigan Society of Thoracic and Cardiovascular Surgeons (MSTCVS) – BCBSM Quality Collaborative already has a viable program for monitoring performance in place, the Committee felt strongly that no other mechanism was necessary or appropriate currently, but that all programs should be mandated to participate in the STS database and the program's state-wide auditing.
- The methodology in the Standards was dated (from 1986) and the listing of ICD-9-CM Codes had to be reviewed and updated before consideration of volumes. A Sub-committee was formed and completed the task of evaluating current codes in use, their appropriateness, and recommended some additional codes. MDCH ran test data from several hospitals to determine the effects of the revised coding and the SAC was satisfied that the volume result variance was insignificant.
- After lengthy discussion, the SAC decided to recommend that the institutional standard of 300 adult open heart surgery cases be maintained. In addition, no changes were recommended for the current institutional standard of 100 pediatric open heart surgery cases.
- The SAC recommends that each physician credentialed by an applicant hospital to perform adult open heart surgery cases, as the attending physician, shall perform a minimum of 75 adult open heart surgery cases per year; this is a revision from 50 adult open heart cases per year.
- Currently a consulting hospital's open heart program must perform a minimum of 350 cases per year; the SAC recommends raising the minimum to 400 cases per year, for 3 consecutive years.
- The SAC had lengthy discussions regarding MIDB data commitments, and recommends several changes related to length of commitment and re-use of data; however, we are awaiting an opinion from the Attorney General's office before making our firm recommendation.

All of the above points will be covered in greater detail in the OHS SAC's Final Report.

**MDCH SUMMARY FOR THE CERTIFICATE OF NEED (CON) COMMISSION
HOSPITAL BED SAC AND COMMISSION ACTIVITY
June 13, 2007 Commission Meeting**

PROCESS OVERVIEW

The Commission requested that the Department compile a brief summary of previous SAC and Commission actions related to CON hospital bed discussions. It is important to note that this topic has been the subject of ongoing and broad-based discussions by the Commission, two formal Standard Advisory Committees (SACs), several workgroups, and members of the public. The CON process which encompasses a comprehensive and thorough periodic review of all CON standards, including Hospital Bed standards, further provides opportunity for both public and legislative oversight for all proposed changes to the existing standards.

The Hospital Bed standards were reviewed in 2004 and in 2006 through formal bodies of the CON Commission; two separate Hospital Bed SACs. The Commission provided specific charges to these two bodies reflecting key issues that the Commission desired to address as part of its comprehensive review of the standards. As a follow-up to the 2006 SAC activity, the Commission charged the Department to conduct a fact-finding exercise to further explore the issue of hospital bed needs in Michigan. These three separate, but related, activities are described more in depth later in this summary.

SAC composition criteria are precisely crafted to reflect a broadly based and representative body of experts who can address specific CON standards. The SAC must include:

- two-thirds experts with professional competence in the subject matter;
- representatives of health care provider organizations;
- representatives of organizations concerned with licensed health facilities or licensed health professions;
- representatives of organizations concerned with health care consumers;
- and the purchasers and payers of health care services.

Furthermore, the Commission's SACs are time-limited and must complete the assigned charge within a 6-month time period. Consequently, members on each of the two SACs that worked on the hospital bed review standards each represented a thoughtful and informed constituency of Michigan citizens interested in the network of hospitals serving Michigan.

All recommendations, and potential new language, presented to the Commission by the two SACs were made available to the public and discussed in detail by the full Commission. The Commission then made a decision regarding which, if any, of the SAC recommendations would be proposed to move forward for formal public review and public hearing, no less than 30 days prior to the Commission taking any final action on the recommendations. It is only after the general public has had the opportunity to provide input to the proposed action of the Commission that the Commission will take final action to move any modified language forward.

A key element to the oversight of any potential changes to existing standards is a review by the Joint Legislative Committee (JLC). The JLC includes the chairs of key standing committees from both the Senate and the House of Representatives. After the CON

Commission has taken proposed action and no less than 30 days prior to the Commission taking final action, a Public Hearing is conducted by the Commission. The proposed action along with a brief summary of the impact of any changes is sent to the JLC for its review. Upon the Commission taking final action, the JLC and the Governor are provided notice of the proposed final action as well as a brief summary of the impact of any changes that have been proposed by the CON Commission. The JLC and Governor have a 45-day review period to disapprove the proposed final action. Such 45-day review period shall commence on a legislative session day and include 9 legislative session days. If the proposed final action is not disapproved, then it becomes effective upon the expiration of the 45-day review period or on a later date specified in the proposed final action.

It is imperative to keep in mind that the CON Commission takes the steps necessary to assure a comprehensive review of the CON review standards. The Commission further assures that all stakeholders, including Michigan's Legislature, are actively involved in the reviews and discussions leading to any potential modifications of existing standards. Finally, the Commission bases its final decisions upon full and complete information available and with the participation of all interested parties.

SAC March 2004:

In March of 2004, the Commission established a Hospital Bed SAC to initiate a "Prompt review of the Hospital Bed Standards...related to 'the increase of licensed beds in a hospital...the physical relocation of hospital beds from one licensed site to another geographic location, and the replacement of beds in a hospital...'"

The SAC had a membership of 18 individuals appointed to carry out the given charge. The SAC itself formed two distinct workgroups; a Technical Workgroup that included 25 members, and the Comparative Review Workgroup that included 12 members. Although the workgroups included some SAC members, due to limitations placed upon the SAC members by the Open Meetings Act provisions, the participation on the workgroups actually provided a broader representation of interested stakeholders. This greater level of participation by non-SAC members facilitated a broader discussion of the Hospital Bed standards under review.

Upon convening, the SAC identified, and the Commission added, an issue that was not included in the original charge but that the members thought needed to be addressed. This issue was that the SAC draft special bed allocation language that would grant the Department the authority to approve new hospitals with relocated beds without a determination of need using utilization or access methodologies.

The SAC completed its work in November 2004, and presented its report along with recommendations to the Commission at its December 14, 2004 quarterly meeting. The SAC recommended a "high occupancy" component be added to the standards, recommended language to identify "limited access areas," did not support any changes to the hospital bed methodology, did not support any change to the two mile replacement zone, and did not

support any additional changes that would allow the relocation of licensed beds from one licensed site to another geographic location (unlicensed site).

Regarding the additional charge of allowing for the creation of new hospitals with relocated beds within an HSA if certain criteria were met (no increase of beds in the HSA); the SAC did not support this recommendation.

Along with these specific recommendations directly related to its charge, the SAC further recommended the establishment of a new SAC for the purpose of addressing issues that the original SAC was unable to complete within its 6-month time frame, or that had been newly identified during the SAC activity. Issues recommended for consideration by a new SAC included: Conduct a travel time analysis to include consideration of capacity of existing hospitals; consideration of pediatric and other specialty occupancy issues; development of comparative review criteria for all hospital bed applications; and consideration of access issues associated with public transportation, racial and ethnic diversity, cultural competency, and sensitivity to language barriers as project delivery requirements.

The CON Commission accepted the recommendations of the SAC and moved the recommendations forward for final action. The new review standards became active on 5/27/05.

SAC September 2005:

At its September 13, 2005, meeting, the Commission developed a charge which included the elements recommended by an earlier SAC. The charge sought recommendations for the first three recommendations and added a review of current replacement zones, the impact of occupancy levels on the bed need methodology, and some thinking about multiple-site licensing for facilities under common ownership. The Department moved forward to take applications for a second Hospital Bed SAC. This SAC met as a whole for a total of seven meetings; additionally, it conducted its work by breaking out into four different subcommittees that met regularly during the life of the SAC. Each of the four subcommittees assumed responsibility for distinct portions of the charge to the SAC, and for presenting suggestions to the SAC for its consideration. Approximately 19 meetings of the four subcommittees were held during the six month time period, with an undetermined number of "workgroup" sessions of these four subcommittees bringing back information to the group. These subcommittees, with their respective workgroups, were open to any organization or individual who wished to participate, thus, there was no formal "membership." The size of these workgroups ranged from approximately six to approximately 25 depending on the identified agenda. Materials were mailed to any individual requesting that their name be included in any mailings that were distributed.

The SAC presented its final report to the Commission at the September 2006 Commission meeting; offering draft language and identifying two unresolved issues for which the SAC members had differing points of view. The issues of replacement zones and comparative reviews could not be resolved by the SAC members and a single recommendation could not be made to the Commission. The SAC recommended no additional work needed on travel

time analysis; supported language to add a 10% occupancy factor for pediatrics and obstetrics; supported some expansion of the comparative review standards for hospitals; retained the two mile replacement zone in metropolitan counties; looked into the issues of occupancy and multiple site licensing but offered no further discussion.

The CON Commission accepted the recommendations of the SAC and moved the recommendations forward for final action. The new review standards became effective on 3/8/07.

MDCH Hospital Bed Fact-Finding Task 2006:

At its September 2006, meeting, the Commission made a decision to move the modified standards that had been proposed by the SAC forward for public review and comment. The Commission further directed the Michigan Department of Community Health to review the hospital bed issue and, in particular, the SAC's outstanding issue of comparative review.

In December 2006, the Department brought together a group of hospital representatives, organizations, and individuals to assist with a review of the hospital bed topic including the question of what criterion should be required for making a determination of establishing a new facility in any part of the state. The group met on several occasions and requested information and data from the participants, jointly and individually, to assure as comprehensive a review as possible of the subject at hand. The Department also provided the participants with several research and data documents to facilitate the discussion. Hospital specific information from the individual participants was requested, in writing, at least two times; however, data was not provided to the group.

The fact-finding group was unable to reach a level of consensus on any of the issues brought before it, and the Department could not develop specific recommendations as a direct result of any input from the group as a whole. At the March 2007 meeting of the Commission, the Department reported on its fact-finding group activity and further noted that no additional meetings of this group would be scheduled at this time.

The Commission, at the March 2007 meeting, asked that the Department compile a brief summary and description of the SAC and committee activities related to hospital bed standards.

In conclusion, it is clear that the Hospital Bed Standards generate a tremendous amount of interest and discussion for the Commission. The standards are again scheduled for review in 2008, and it is anticipated that some, or all, of the previously raised questions will be raised again.

CERTIFICATE OF NEED
Quarterly Program Section Activity Report to the CON Commission
 January 1, 2007 through March 31, 2007 (FY 2007)

This quarterly report is designed to assist the CON Commission in monitoring and assessing the operations and effectiveness of the Program Section in accordance with Section 22215(1)(e) of the Public Health Code.

Measures

Administrative Rule 325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

Activity	Most Recent Quarter	Year-to-Date
Letters of Intent Received	142	284
Letters of Intent Processed within 15 days	142	283

Administrative Rule 325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application.

Activity	Most Recent Quarter	Year-to-Date
Applications Received	66	155
Applications Processed within 15 Days	66	155
Applications Incomplete/More Information Needed	60	141

Administrative rules 325.9206 and 325.9207 requires the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Nonsubstantive Applications	24	0	75	0
Substantive Applications	44	0	92	0
Comparative Review Applications	3	0	10	0

Note: Data in this table may not total/correlate with application received table because receive and processed dates may carry over into next month/next quarter.

Administrative Rule 325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

Activity	Most Recent Quarter	Year-to-Date
Emergency Applications Received	0	3
Decisions Issued within 10 workings Days	0	3

Measures – continued

Administrative Rule 325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Amendments	18	0	30	0

Section 22231(10) of the Public Health Code requires the Department to issue a refund of the application fee, upon written request, if the Director exceeds the time set forth in this section for other than good cause as determined by the Commission.

Activity	Most Recent Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	Most Recent Quarter	Year-to-Date
FOIA Requests Received	52	86
FOIA Requests Processed on Time	52	86
Number of Applications Viewed Onsite	49	107

FOIA – Freedom of Information Act.